DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225, Silver Spring, MD 20993-0002 Phone: (301) 796-3334, Fax: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	12/07/2016-12/16/2016* FEI NUMBER 3008307735

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Pabbati Reddy Bhaskar Reddy, Vice President Operations

FIRM NAME	STREET ADDRESS
Hetero Labs Limited	TSIIC Pharma SEZ
CITY, STATE, ZIP CODE, COUNTRY Polepally Village, Jadcherla Mandal, Mahaboob Nagar District, Telangana State, 509301, India	TYPE ESTABLISHMENT INSPECTED Oral Solid Dose Drug Product Manufacturer

This document lists observations made by the FDA representatives during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representatives during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

(1) Specifically, your QA technicians and other individuals were recorded destroying and altering records pertaining to commercial batch manufacturing immediately prior to this regulatory inspection. The loss of data and documents are evidenced by the following:

Through a review of your firms Closed Circuit TV we identified the following:

(a) A document shredder was introduced into your firm's "DOCUMENTS STORAGE AREA" on December 03, 2016 at 15:44, approximately 4 days prior to the current US FDA inspection.

(b) After introduction of the document shredder we observed extensive shredding of what appears to be controlled documents and extensive signing of documents by QA. These documents were of a color consistent with batch packaging records and batch manufacturing records, among other documents. Your firm failed to maintain documentation of what had been shredded.

(c) On December 06, 2016, at (b) (4) we observed that a contract employee with QA removed documents from the shredder and placed them in his pocket.

(d) On December 07, 2016, at approximately 1:13 (in the middle of the night) individuals were shredding documents. Your firm stated this event represented cleaning staff shredding documents.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Massoud Motamed, Investigator Latorie S. Jones, Investigator	12/16/2016

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(e) Other anomalous events were observed associated with this shredder. Your firm failed to clarify the correlation of introducing the shredder to the "DOCUMENTS STORAGE AREA" prior to the current US FDA inspection.

Your firm's Quality Manager stated that your firm has failed to maintain a log of what documents had been shredded and therefore fulfill their position. Under SOP QA001-11 titled "PREPARATION, REVIEW, APPROVAL, CONTROL AND REVISION OF STANDARD OPERATING PROCEDURE, FORMATS AND DOCUMENT CONTROL", Quality Assurance is responsible for "The storage arrangements must make reasonable provision to prevent loss of or damage to the documents."

(2) On December 12, 2016, we observed the scrap area behind the production area of Buildings (b)(4) and (b)(4) to contain controlled documents that had been discarded:

(a) A balance printout with drug product "(b)(4) " dated "14-Dec-2016". *After discussing this finding with your firm, you failed to explain why the balance printout was post-dated by two days, and therefore indicating an alteration to dates on balances.* Your firm's VP of Operations explained that not all balances are password protected.

(b) A "GMP REPORT" indicating a test result of "PASS" with a start date "11/12/16". Your firm's Vice President of Corporate Quality Assurance initially purported that these test results represented a "credit card print from the market."

(c) A printout indicating an "Abort" event of testing.

(d) A plethora of documents with written numbers and signatures.

(3) On December 07, 2016, we observed controlled documents in shred bins, shredders and trash bins as follows:

(a) In the trash bin outside Building (b)(4) we observed the trash liner contained various controlled documents, including: original test results from November 26, 2016 at 12:52 and cleanroom certification reports from (b)(4) 2005. We observed the Hetero seal and official signatures as a part of this discarded record.

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	Massoud Motamed, Investigator Latorie S. Jones, Investigator	12/16/2016